



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|-------------------------|
| 10/632,192 | 07/31/2003 | Jeffrey Corbett | PH 7182 NP | 3953 |
| 23914 | 7590 | 02/09/2005 | | EXAMINER |
| STEPHEN B. DAVIS | | | | TRUONG, TAMTHOM NGO |
| BRISTOL-MYERS SQUIBB COMPANY | | | | |
| PATENT DEPARTMENT | | | ART UNIT | PAPER NUMBER |
| P O BOX 4000 | | | | 1624 |
| PRINCETON, NJ 08543-4000 | | | | |
| | | | | DATE MAILED: 02/09/2005 |

Please find below and/or attached an Office communication concerning this application or proceeding.

D

| | | | |
|------------------------------|-------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/632,192 | CORBETT, JEFFREY | |
| | Examiner Tamthom N. Truong | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10-27-03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Claims 1-15 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-13 recite many drugs by their abbreviations (e.g., 3TC, AZT, MKC-442, RD4-2025, etc.) which have no legend in the specification as to what compounds they represent. Applicant is suggested to use generic names in place of those abbreviations (e.g., delavirdine, efavirenz, nevirapine, etc.).
2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph for reciting the limitation "hydrogen" in R³. There is insufficient antecedent basis for this limitation in the claim. That is, claim 7 recites two species in which R³ is hydrogen, which is not recited in the independent claim 1.
3. Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "one of claim 1", which is unclear as to the dependency of these claims. That is, it is not clear if claims 9-15 are intended as multiple dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rabel et. al.** (US 6,225,317 B1) in view of **Rodgers et. al.** (WO 00/00479).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The teaching of Rabel et. al. discloses the crystalline of *(-)-6-Chloro-4-cyclopropylethynyl-4-trifluoromethyl-3,4-dihydro-2(1H)-quinazolinone*, which is used to treat HIV infection. Said compound is analogous to the second compound of claim 7, which is *6-Chloro-4-(1-methyl-cyclopropylethynyl)-4-trifluoromethyl-3,4-dihydro-2(1H)-quinazolinone*. The disclosed compound differs from the claimed compound by not having a **methyl** group on the cyclopropyl ring. It also differs from compounds in the instant claims 1-7 by not having an

alkyl or cyclopropyl group at the 3rd position (or on the nitrogen of the quinazolinone). Said differences can be overcome by the teaching of Rodgers et. al. (WO'479). On pages 95-102, Rodgers et. al. disclose the following benzodiazepin-2-one compounds:

Compound #6, substituted with a 7-Cl, CF₃, cyclopropylethynyl, and CH₃ (on the ring nitrogen);

Compound #7, substituted with a 7-Cl, CF₃, cyclopropylethynyl, and Et (on the ring nitrogen);

Compound #8, substituted with a 7-Cl, CF₃, cyclopropylethynyl, and cyclopropyl (on the ring nitrogen);

Compound #41, substituted with a 7-Cl, CF₃, (1-methyl-cyclopropylethynyl);

Compound #89, substituted with a 7-Cl, CF₃, cylopropylvinyl;

The above cited compounds show an **equivalent teaching** for (1-methyl-cyclopropylethynyl), cyclopropylethynyl, and cylopropylvinyl. They also show an **equivalent teaching** for substituents on the ring nitrogen such as hydrogen, CH₃, Et, and cyclopropyl. All of these compounds can also treat HIV infection.

Therefore, the teaching of Rodgers would have motivated one skilled in the art to replace cyclopropylethynyl in the compound of Rabel et. al. with **(1-methyl-cyclopropylethynyl)**. Likewise, one would have been motivated to replace the cyclopropylethynyl in (1-methyl-cyclopropylethynyl) with cyclopropylvinyl to obtain a subsituent of (1-methyl-cyclopropylvinyl). Similarly, one would have been motivated to replace hydrogen on the ring nitrogen in the compound of Rabel et. al. with CH₃, Et, or cyclopropyl. Such a replacement would have still maintained the activity of Rabel's compound in the treatment of HIV infection.

Both Rabel et. al. and Rodgers et. al. further teach a pharmaceutical composition and a method of treating HIV infection either by their compounds alone, or by combining their

Art Unit: 1624

compounds with either a reverse transcriptase inhibitor or a protease inhibitor (see column 15, lines 1-35 of US'317; and pages 157-158, claims 12-16 of WO'479) as recited in the instant claims 8-15.

Therefore, at the time of the invention, it would have been obvious to one of the ordinary skill in the art to make and use the claimed quinazolinone compounds in view of the combined teachings above.

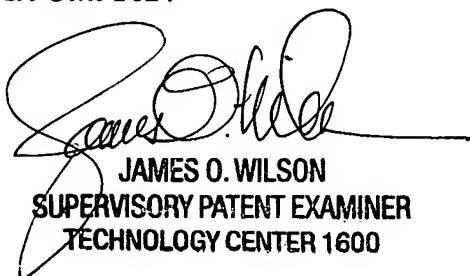
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

2-5-05


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600